RECEIVED AT DRUG SAFETY SURVEILLANCE
27-JAN-1998-0127

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McN
McNEIL CONSUMER P
FORT WASHING

Individual Safety Report
301S487-4-00

Page ____ of ____

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event: / Date of birth:	3. Sex	4. Weight
[redacted] In confidence	or adult	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(X) death unk date (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event: unknown (mo/day/yr)

4. Date of this report: 01/19/98 (mo/day/yr)

5. Describe event or problem

Notification by attorney's office & Writ of Summons of HEPATIC FAILURE and DEATH allegedly associated with the use of an Extra Strength TYLENOL® acetaminophen product in an adult female client. No further information was provided.

PFC.

6. Relevant tests/laboratory data, including dates

unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product

#2

2. Dose, frequency & route used

#1 unknown dose

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown dates or duration

#2

4. Diagnosis for use (indication)

#1 unknown

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown

#2

7. Exp. date (if known)

#1 Unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
(x) other: attorney

4. Date received by manufacturer (mo/day/yr): 01/15/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

DEATH LIVER FAILURE

9. Mfr. report number

0918361A

E. Initial reporter

1. Name, address & phone #

[redacted] Street

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes (X) No	attorney	( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.